

Amendments to the Claims:

1. (Previously cancelled)
2. (Previously cancelled)
3. (Previously amended) The medical device of claim 60, wherein said vector is an adenoassociated virus vector.
- 4-9 (Previously cancelled)
10. (Previously amended) The medical device of claim 60, wherein said vector comprises a viral vector.
11. (Original) The medical device of claim 10, wherein said vector is thermostable, replication-deficient, non-immunogenic, or a combination thereof.
12. (Previously amended) The medical device of claim 60 wherein said expression is achieved in about 20% to about 80% of cells exposed to said genetic material.
- 13-16 (Previously cancelled)
17. (Previously amended) The medical device of claim 60, wherein said polymeric coating comprises polyurethane, silicone, EVA, poly-l-lactic acid /poly ϵ -caprolactone blends, or a combination thereof.
18. (Previously amended) The medical device of claim 60, wherein said polymer coating is from about 1 to about 40 layers having a thickness of from about 1 to about 10 μm / layer of coating.
19. (Previously amended) The medical device of claim 60, wherein said structure is a stent.
20. (Original) The medical device of claim 19, wherein said stent is a metallic stent.

21-22

23. (Previously amended) The medical device of claim 60, wherein said therapeutic agent and said vector are applied onto or impregnated into a same layer of said polymer coating.

24. (Previously amended) A method of inhibiting or treating restenosis in a patient, said method comprising administering at a predetermined site within the body of said patient the device of claim 60.

25. (Previously amended) The method of claim 24, wherein said site is a site of mechanical injury to an arterial wall produced by treatment of an atherosclerotic lesion by angioplasty.

26. (Previously cancelled)

27. (Previously amended) The method of claim 62, wherein said vector is adenoassociated virus vector.

28-33 (Previously cancelled)

34. (Previously amended) The method of claim 62, wherein said vector comprises a viral vector.

35. (Original) The method of claim 34, wherein said viral vector is thermostable, replication-deficient, non-immunogenic, or a combination thereof.

36. (Previously amended) The method of claim 62, wherein said expression is achieved in about 20% to about 80% of cells exposed to said genetic material.

37. (Previously amended) The method of claim 62, wherein said vector is a delayed expression vector.

38. (Original) The method of claim 37, wherein said delayed expression is an expression delayed from about two days to about 3 weeks after administration in vivo.

39. (Previously cancelled)

40- 41 (Previously cancelled)

42. (Previously amended) The method of claim 62, wherein said coating comprises polyurethane, silicone, EVA, poly-l-lactic acid /poly G-caprolactone blends, or a combination thereof.

43. (Previously amended) The method of claim 62, wherein said polymer coating is from about 1 to about 40 layers having a thickness of from about 1 to about 10 μ m/ layer of coating.

44. (Previously amended) The method of claim 62, wherein said structure is a stent.

45-46 (Previously Cancelled)

47. (Original) The method of claim 44, wherein said stent is a metallic stent.

48-53 (Previously Cancelled)

54. (Previously amended) The medical device of claim 60, wherein said vector contains regulatory sequences.

55. (Previously amended) The method of claim 62, wherein said vector comprises liposomes, lipofectin, lipoplexes, polyplexes, dextrans, starburst, dendrimer conjugates, polybenzene dimethyl sulfoxide, protamine sulfate, antibody conjugates, polylysine conjugates, gramicidin S, artificial conjugates, viral envelopes, viral-like particles, nano or micro particles, or a combination thereof.

56-57 (Previously cancelled)

58. (Previously amended) The method of claim 62, wherein said vector is a delayed expression vector.

59. (Previously amended) The method of claim 62, wherein said vector contains regulatory sequences.

60. (Currently amended) A medical device comprising:
a biocompatible structure comprising a polymeric coating that coats at least a portion of said structure, said polymeric coating comprising:

(A) a therapeutic agent, said therapeutic agent selected from the group consisting of

- (1) an angiogenic agent, wherein the angiogenic agent is an acidic fibroblast growth factor, basic fibroblast growth factor, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, or insulin growth factor;
- (2) an agent that enhances gene transfer and integration into tissue and cells;
- (3) a immunosuppressant;
- (4) an antiangiogenic agent;
- (5) an antithrombogenic agent;
- (6) tissue plasminogen activator;
- (7) erythropoietin;
- (8) an antioxidant;
- (9) an agent blocking smooth muscle proliferation;
- (10) an anti-inflammatory agent;
- (11) a calcium entry blocker;
- (12) an antineoplastic;
- (13) an antiproliferative or anti-mitotic agent;
- (14) an anesthetic agent;
- (15) an anticoagulant;
- (16) an anti-thrombin antibody;
- (17) an anti-platelet receptor antibody;
- (18) a prostaglandin inhibitor;
- (19) a platelet inhibitor;
- (20) a vascular cell growth promoter;
- (21) a growth factor receptor antagonist;
- (22) a transcriptional activator;
- (23) a translational promoter;
- (24) a vascular cell growth inhibitor;
- (25) a growth factor receptor antagonist;
- (26) a transcriptional repressor;
- (27) a translational repressor;
- (28) a replication inhibitor;
- (29) an inhibitory antibody;
- (30) an antibody directed against a growth factor;
- (31) a bifunctional molecule consisting of a growth factor and a cytotoxin;
- (32) a cholesterol-lowering agent;
- (33) a vasodilating agent;
- (34) an agent which interferes with endogenous vasoactive mechanisms; and
- (35) a cell cycle inhibitors;

and

(B) a vector containing a polynucleotide that establishes a gene expression sufficient to produce a therapeutically sufficient amount of one or more products encoded by said polynucleotide, wherein said polynucleotide encodes a polypeptide or protein, said polypeptide or protein selected from the group consisting of

~~(1) an angiogenic agent, wherein the angiogenic agent is an acidic fibroblast growth factor, basic fibroblast growth factor, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet derived endothelial growth factor, platelet derived growth factor, tumor necrosis factor α , hepatocyte growth factor, or insulin growth factor;~~

(2) an antiangiogenic agent;

(3) an antithrombogenic agent;

(4) tissue plasminogen activator;

(5) erythropoietin;

(6) an antioxidant;

(7) an agent blocking smooth muscle proliferation;

(8) an anti-inflammatory agent;

(9) a calcium entry blocker;

(10) an antineoplastic;

(11) an antiproliferative or anti-mitotic agent;

(12) an anesthetic agent;

(13) an anticoagulant;

(14) an anti-thrombin antibody;

(15) an anti-platelet receptor antibody;

(16) a prostaglandin inhibitor;

(17) a platelet inhibitor;

(18) a vascular cell growth promoter;

(19) a growth factor receptor antagonist;

(20) a transcriptional activator;

(21) a translational promoter;

(22) a vascular cell growth inhibitor;

(23) a growth factor receptor antagonist;

(24) a transcriptional repressor;

(25) a translational repressor;

(26) a replication inhibitor;

(27) an inhibitory antibody;

(28) an antibody directed against a growth factor;

(29) a bifunctional molecule consisting of a growth factor and a cytotoxin;

(30) a cholesterol-lowering agent;

(31) a vasodilating agent;

(32) an agent which interferes with endogenous vasoactive mechanisms; and
a cell cycle inhibitors

(33) an anti-restenosis agent;

(34) a monocyte chemoattractant protein;

(35) a bone morphogenic protein;

(36) a hedgehog protein and

(37) a cell cycle inhibitors; and

combinations thereof

wherein the angiogenic agent is an acidic fibroblast growth factor, basic fibroblast growth factor, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, or insulin growth factor.

61. (Cancelled)

62. (Currently amended) A method of controlled delivery of a genetic material to a mammalian body comprising:

(A) applying a polymer coating to at least a portion of a medical device;

(B) applying a genetic material to said polymer coating to obtain a genetically coated medical device, said genetic material comprising:

(i) a therapeutic agent, said therapeutic agent selected from the group consisting of

(1) an angiogenic agent, wherein the angiogenic agent is an acidic fibroblast growth factor, basic fibroblast growth factor, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, or insulin growth factor;

(2) an agent that enhances gene transfer and integration into tissue and cells;

(3) a immunosuppressant;

(4) an antiangiogenic agent;

(5) an antithrombogenic agent;

(6) tissue plasminogen activator;

(7) erythropoietin;

(8) an antioxidant;

(9) an agent blocking smooth muscle proliferation;

(10) an anti-inflammatory agent;

(11) a calcium entry blocker;

(12) an antineoplastic,

(13) an antiproliferative or anti-mitotic agent;

(14) an anesthetic agent;

(15) an anticoagulant;

(16) an anti-thrombin antibody;

(17) an anti-platelet receptor antibody;

(18) a prostaglandin inhibitor;

- (19) a platelet inhibitor;
- (20) a vascular cell growth promoter;
- (21) a growth factor receptor antagonist;
- (22) a transcriptional activator;
- (23) a translational promoter;
- (24) a vascular cell growth inhibitor;
- (25) a growth factor receptor antagonist;
- (26) a transcriptional repressor;
- (27) a translational repressor;
- (28) a replication inhibitor;
- (29) an inhibitory antibody;
- (30) an antibody directed against a growth factor;
- (31) a bifunctional molecule consisting of a growth factor and a cytotoxin;
- (32) a cholesterol-lowering agent;
- (33) a vasodilating agent;
- (34) an agent which interferes with endogenous vasoactive mechanisms; and
- (35) a cell cycle inhibitors;

and

(ii) a vector containing a polynucleotide that establishes a gene expression sufficient to produce a therapeutically sufficient amount of one or more products encoded by said polynucleotide, wherein said polynucleotide encodes a polypeptide or protein, said polypeptide or protein selected from the group consisting of

- (1) an angiogenic agent, ~~wherein the angiogenic agent is an acidic fibroblast growth factor, basic fibroblast growth factor, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, or insulin growth factor;~~
- (2) an antiangiogenic agent;
- (3) an antithrombogenic agent;
- (4) tissue plasminogen activator;
- (5) erythropoietin;
- (6) an antioxidant;
- (7) an agent blocking smooth muscle proliferation;
- (8) an anti-inflammatory agent;
- (9) a calcium entry blocker;
- (10) an antineoplastic;
- (11) an antiproliferative or anti-mitotic agent;
- (12) an anesthetic agent;
- (13) an anticoagulant;
- (14) an anti-thrombin antibody;
- (15) an anti-platelet receptor antibody;

- (16) a prostaglandin inhibitor;
- (17) a platelet inhibitor;
- (18) a vascular cell growth promoter;
- (19) a growth factor receptor antagonist;
- (20) a transcriptional activator;
- (21) a translational promoter;
- (22) a vascular cell growth inhibitor;
- (23) a growth factor receptor antagonist;
- (24) a transcriptional repressor;
- (25) a translational repressor;
- (26) a replication inhibitor;
- (27) an inhibitory antibody;
- (28) an antibody directed against a growth factor;
- (29) a bifunctional molecule consisting of a growth factor and a cytotoxin;
- (30) a cholesterol-lowering agent;
- (31) a vasodilating agent;
- (32) an agent which interferes with endogenous vasoactive mechanisms; and
a cell cycle inhibitors
- (33) an anti-restenosis agent;
- (34) a monocyte chemoattractant protein;
- (35) a bone morphogenic protein;
- (36) a hedgehog protein and
- (37) a cell cycle inhibitors; and
combinations thereof

wherein the angiogenic agent is an acidic fibroblast growth factor, basic fibroblast growth factor, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, or insulin growth factor; and

(C) inserting or implanting said genetically coated medical device at a predetermined site in said mammal.

63. (New) The medical device of claim 60, wherein the therapeutic agent is an angiogenic agent selected from the group consisting of an acidic fibroblast growth factor, basic fibroblast growth factor, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, and insulin growth factor; and the polypeptide or protein encoded by said polynucleotide is an angiogenic agent selected from the group consisting of acidic fibroblast growth factors, basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, and insulin growth factor.

64. (New) The method of claim 62 wherein the therapeutic agent is an angiogenic agent selected from the group consisting of an acidic fibroblast growth factor, basic fibroblast growth factor, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, and insulin growth factor; and the polypeptide or protein encoded by said polynucleotide is an angiogenic agent selected from the group consisting of acidic fibroblast growth factors, basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor, and insulin growth factor.